

6477. (F.D.C. No. 44661. S. Nos. 57-204 P, 72-489 P.)

INFORMATION FILED: 9-13-60, S. Dist. Ga., against Ellsworth O. Fish (an employee of a restaurant on U.S. Highway No. 301, in Long County, Ga.).

CHARGE: On 9-21-59, *amphetamine sulfate tablets* were dispensed twice without a prescription.

DISPOSITION: On 2-9-61, the case was transferred to the Southern District of New York for the entry of a plea of guilty. On 3-6-61, the defendant entered a plea of guilty and was placed on probation for 6 months.

6478. (F.D.C. No. 43701. S. Nos. 53-345 P, 53-579 P, 53-581/2 P.)

INFORMATION FILED: 1-29-60, Dist. Nev., against Nicholas Eugene Thomsen, t/a Nick's Drug, Las Vegas, Nev.

CHARGE: Between 7-23-59 and 8-13-59, *secobarbital sodium capsules* were dispensed once and *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 6-24-60. Imprisonment for 1 year.

6479. (F.D.C. No. 43723. S. Nos. 45-884/7 P, 45-889/93 P.)

INFORMATION FILED: 3-1-60, N. Dist. Miss., against James W. Listenbee, t/a Listenbee's Drug & Dept. Store, Calhoun City, Miss.

CHARGE: Between 1-20-59 and 1-27-59, *phenobarbital tablets* were dispensed 3 times, *prednisone tablets* were dispensed twice, and *penicillin tablets*, *thyroid tablets*, *Tuinal capsules*, and *meprobamate tablets* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 5-27-60. \$900 fine.

6480. (F.D.C. No. 45204. S. Nos. 29-173/5 R, 29-177/8 R, 29-939 R, 29-942/4 R.)

INFORMATION FILED: 1-24-61, S. Dist. Iowa, against Otis C. Webb, Jr., t/a Douglas Pharmacy, Des Moines, Iowa.

CHARGE: Between 9-9-60 and 9-14-60, *phenobarbital tablets* were dispensed twice upon requests for prescription refills without authorization by the prescriber, and *amphetamine sulfate tablets* were dispensed 6 times and *methyl-testosterone tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2-20-61. Imprisonment for 1 year.

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6481-6500

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent; (2) a criminal proceeding terminated upon a plea of guilty; and (3) an injunction proceeding terminated upon the entry of a permanent injunction by consent. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., March 23, 1962.

CONTENTS*

	Page		Page
New drugs shipped without effective application.....	350	Drugs and device actionable because of deviation from official or own standards.....	355
Violative sales of prescription drugs.....	351	Drugs and device actionable because of false and misleading claims.....	359
Drugs actionable because of failure to bear adequate directions or warning statements.....	352	Index.....	370

*For presence of a habit-forming substance without warning statements, see No. 6481; an imitation of, and sale under name of, another drug, No. 6482; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 6484.

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D.D.N.J. NOS. 6481-6500**

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, or its quality fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b)(1), the article was in package form, and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502(d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; and Section 503(b)(1), the article was dispensed without a prescription from a practitioner licensed by law to administer the article.

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6481. Delfetamine Stedytabs and Delfeta-Sed Stedytabs. (F.D.C. No. 44603. S. Nos. 4-020/1 R.)

QUANTITY: 2 drums, each containing about 50,000 tablets, and 118 30-tablet ctns., of *Delfetamine Stedytabs*, and 278 30-tablet ctns., of *Delfeta-Sed Stedytabs*, at Baltimore, Md., in possession of Eastern Research Laboratories, Inc.

SHIPPED: Between 11-16-58 and 3-21-60, from St. Louis, Mo., by Victor M. Hermelin & Co.

LABEL IN PART: (Drum) "Delfetamine, 30 Mg. Stedytabs Each tablet contains: *Delfetamine 30 mg. Caution * * * Average dose * * * Manufactured by a special process * * * to provide prolonged continuous therapeutic effect from active ingredient over a period up to 8-12 hours. *Registered Trademark of dl-N-methyl-beta-phenylisopropylamine Hydrochloride. Victor M. Hermelin and Company, New Products Division of K-V Pharmacal Company, St. Louis 17, Missouri"; (ctn.) "Stedytabs Sustained Release Tablets Delfetamine dextro-levo N-methylamphetamine HCl * * * Eastern Research Laboratories, Inc., Baltimore 1, Maryland"; and "Stedytabs Sustained Release Tablets Delfeta-sed Delfetamine With Sedafax * * * Eastern Research Laboratories, Inc., Baltimore 1, Maryland."